



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/843,181	04/26/2001	Chris Sikorski	CER-298	9166

20311 7590 11/25/2003

MUSERLIAN AND LUCAS AND MERCANTI, LLP
475 PARK AVENUE SOUTH
NEW YORK, NY 10016

EXAMINER

WHITE, EVERETT NMN

ART UNIT	PAPER NUMBER
----------	--------------

1623

DATE MAILED: 11/25/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/843,181

Applicant(s)

SIKORSKI ET AL.

Examiner

EVERETT WHITE

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-13 and 15-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-13 and 15-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

1. The amendment filed September 12, 2003 has been received, entered and carefully considered. The amendment affects the instant application accordingly:
 - (A) Claims 1-6 and 14 were previously canceled;
 - (B) New Claim 19 has been added;
 - (C) Claims 7 and 12 have been amended;
 - (D) Comments regarding Office Action have been provided drawn to:
 - (i) 112, 2nd paragraph rejection, which has been withdrawn; and
 - (ii) 103(a) rejection, which has been maintained for the reasons of record.
2. Claims 7-13 and 15-19 are pending in the case.
3. The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.

The Declaration By Chris Sikorski Noted

4. The declaration presented by Chris Sikorski filed September 12, 2003 to proffer allowable subject matter over prior art is noted. The declaration presents a comparison between a drum drying technique as claimed and a spray drying technique of the prior art. The Examiner acknowledges the advantages of the drum drying technique over the spray drying technique, but does not indicate the instantly claimed invention as possessing allowable subject matter in view of the declaration since the spray drying technique does not represent the closest prior art.

Claim Rejections - 35 USC § 103

5. Claims 7-11 and 19 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Shah et al (US Patent No. 6,153,746) in view of Walsh (US Patent No. 5,980,971) or Giacobello (US Patent No. 4,127,944) for the reasons set forth on pages 3 and 4 of the Office Action mailed June 12, 2003.
6. Applicant's arguments filed September 12, 2003 have been fully considered but they are not persuasive. It is noted that Applicants amended Claim 7 by changing the phrase "double drum dryer" to - - drum dryer - -.

Applicants argue against the rejection of the claims on the ground that none of the cited references teaches the particle size distribution improvements can be made to an agglomerated uncomplexed modified cyclodextrin product by drying a solution of uncomplexed modified cyclodextrin on a drum dryer. However, this argument is not persuasive since it is noted that the process steps of Claim 7 for obtaining the product thereof having the recited particle distribution is drying an aqueous solution of uncomplexed modified cyclodextrin on a drum dryer. No other process step has been set forth which would substantially manipulate the particle distribution. The Shah et al patent sets forth a procedure wherein a sulfoalkyl ether cyclodextrin in an aqueous medium can be submitted to a suitable drying technique which may be selected as vacuum drum drying, which is analogous to the procedure set forth in the instant claims. The sulfoalkyl ether cyclodextrin product of the Shah et al patent is within the scope of the uncomplexed modified cyclodextrin product prepared in the instantly claimed process. Applicants are reminded that products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada* 15 USPQ 2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01. Since the cyclodextrin product of the Shah et al patent and produced by the process of the instant claims are of identical chemical composition, one would expect both products obtained using the same process would result in products having identical properties, including having identical particle distribution as set forth in the instantly claimed process and identical dissolution time as set forth in newly added Claim 19.

Arguments presented by Applicants against the Walsh and Giacobello patents for setting forth different materials to be dried in their drum dryers is noted. However, the Walsh and Giacobello patents are only cited to show the operational ability that is well known for drum dryer apparatuses.

Accordingly, the rejection of Claims 7-11 under 35 U.S.C. 103(a) as being unpatentable over the Shah et al patent in view of the Walsh or Giacobello patents is maintained for the reasons of record.

7. Claims 12, 13, 15-18 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Shah et al (US Patent No. 6,153,746) for the reasons set forth on pages 5 and 6 of the Office Action mailed June 12, 2003.

Applicant's arguments filed September 12, 2003 have been fully considered but they are not persuasive. In view of the argument presented by Applicants, the Majid et al patent (US Pat. No. 5,070,081) has been withdrawn from the rejection, but maintained the rejection of the claims over the Shah et al patent. As argued in the above rejection of the claims, the sulfoalkyl ether cyclodextrin product of the Shah et al patent is within the scope of the uncomplexed modified cyclodextrin product set forth in the instant claims. Applicants are reminded that products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada* 15 USPQ 2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01. Since the cyclodextrin product of the Shah et al patent and produced by the process of the instant claims are of identical chemical composition, one would expect both products obtained using the same process would result in products having identical properties, including having identical particle distribution as set forth in the instant claims. Accordingly, the rejection of Claims 12, 13, 15-18 under 35 U.S.C. 103(a) as being unpatentable over the Shah et al patent is maintained for the reasons of record.

Summary

8. All the pending claims are rejected.

ACTION MADE FINAL

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Examiner's Telephone Number, Fax Number, and Other Information

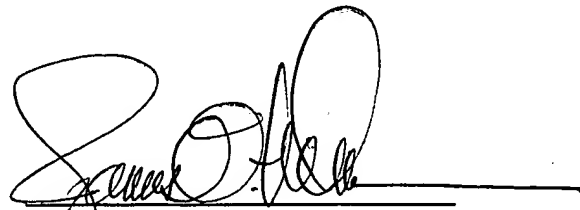
10. For 24 hour access to patent application information 7 days per week, or for filing applications, please visit our website at www.uspto.gov and click on the button "Patent Electronic Business Center" for more information.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Everett White whose telephone number is (703) 308-4621. The examiner can normally be reached on Monday-Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reached on (703) 308-4624. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

E. White
E. White


James O. Wilson
Supervisory Primary Examiner
Technology Center 1600